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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,344	05/23/2005	Jan De Kroon	4662-254	6496

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EXAMINER	
HAIDER, SAIRA BANO	
ART UNIT	PAPER NUMBER
1796	
MAIL DATE	DELIVERY MODE
04/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,344	DE KROON ET AL.	
	Examiner	Art Unit	
	SAIRA HAIDER	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5 and 8-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5, 8-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/29/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 5 and 8-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bayer in view of Johnston.

3. Bayer discloses branched polyamide molding materials that are applied to polyolefin layers to form multilayer films (Col. 2, Line 43 to Col. 3. Lines25; Col. 6, Lines 15-23). Blow molding is noted as a preferred production method for the multilayer films (Col. 5, Line 64 to Col. 6, Line 7).

4. Bayer fails to specify polypropylene or LLDPE as the polyolefins. Hence attention is directed towards the Johnston reference (Column: Lines:: abstract; 2:32-58; 3:68-4:4, 4:21-35, Table 1). Johnston teaches laminate films comprising outer polyolefin layers and a polyamide core layer. The reference teaches that containers are to be formed from the films, and that sterilization temperature controls the selection of the heat sealing inner layer. LLDPE and polypropylene layer are both suggested for the inner layer. LLDPE is also chosen when the sterilized medical product is filled in the container. Polypropylene is one of two materials to be used for the outer layer, especially linear biaxially oriented polypropylene. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to bond the polyamides of Bayer to either or both of polypropylene and LLDPE to provide a sterilizable container usable at a desired sterilization temperature.

5. In reference to claims 12-15 and 22-25, Johnston discloses that the multilayer film has a total thickness of about 75 to about 200 microns. The inner layer comprising either LLDPE or polypropylene has a thickness of about 50 to about 120 microns. The core layer comprising

polyamide has a thickness of about 15 to about 50 microns. Johnston discloses that the combined dimensions of the core, inner and outer layers provide an improved container, if the total thickness is less than 75 microns the impact strength will not be sufficient, and if the total thickness is in excess of 200 microns the container will lack flexibility. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to form the multilayer film, as taught by the combination of Bayer and Johnston, in the aforementioned dimensions in order to ensure sufficient impact strength and flexibility.

6. In reference to claim 17, Bayer and Johnston in combination fail to disclose that the flown film has a blow-up ratio of from 20 to 40 %. It would have been obvious to one of ordinary skill in the art at the time of the invention to control the blow-up ratio, wherein the blow-up ratio of the blown film is a readily manipulatable parameter. The motivation to modify the blow-up ratio is to control the diameter of the final product while blown in the die or mold cavity, instead of modifying the size of the die or cavity. It is noted that the final product of Johnston includes bags and container, in particular for conveying or storing liquids or gases (col. 2, lines 20-32).

1.132 Declaration

7. Applicants have argued the presence of unexpected results due to the use of a branched polyamide layer in a multilayer structure. Applicants have submitted a 1.132 Declaration which summarizes the experimental evidence presented in the specification of the herein application. The examiner has considered the allegation of unexpected results and concludes that the statements and examples provided are insufficient to establish unexpected results.

8. Specifically, attention is directed to comparative experiment A and example 1, wherein the comparative experiment contains a non-branched polyamide and the example contains a branched

polyamide. The difference in the Elmendorf tear strength of the two is 2 kN/m, this difference cannot unequivocally be attributed to the presence or lack thereof of branched polyamides. Rather the difference may readily be attributed to standard error measurements or an expected difference due to the presence or lack thereof of branched polyamides. Further, applicants have alleged an unexpected increase in bubble stability of the inventive examples (Example 1 & Comparative Experiment A; Example I and Comparative Example B). However, there is no explanation of the evidence gathered resulting in the conclusion of the bubble stability of Example I being "markedly better" than in Comparative Experiment A or the conclusion that it is not possible to obtain a bubble of "sufficient stability" with Comparative Experiment B. These statements are not found to be of substantial evidentiary value, since the evidence fails to establish that the differences are in fact unexpected, unobvious. and of both statistical and practical significance. The evidence merely supports the recognized position that the differences (branched and non-branched polyamide and presence/absence of LDPE) in the claimed invention and the prior art are expected to have some differences in properties. The statements are not indicia of unexpected results; rather they are indicia of expected results.

9. The difference in the blow ratio of Example 1 and Example 2 is merely 0.4, wherein this difference cannot unequivocally be attributed to the presence or lack thereof of LDPE. Rather the difference may readily be attributed to standard error measurements or an expected difference due to the presence or lack thereof of branched polyamides.

10. Additionally, the evidence presented is not commensurate in scope with the claims. For example, the claims are open to a polyolefin layer consisting essentially of polypropylene, whereas the examples do not even test polypropylene. Applicants' attention is directed to MPEP §716 which

discloses the requirements for effectively rebutting a *prima facie* case of obviousness based on unexpected results.

Response to Arguments

11. Applicants have argued the presence of unexpected results due to the use of a branched polyamide layer in a multilayer structure. The examiner has considered the arguments and evidence alleging unexpected results and concludes that the statements and examples provided are insufficient to establish unexpected results.

12. Applicant has argued that the proper comparison is that of Example II against Comparative Experiment C. The specification fails to contain a Comparative Experiment C; however the Comparative Example having a non-branched polyamide layer and a LLDPE layer is Comparative Example B. According, the examiner will address the comparison of Example II against Comparative Experiment B.

13. The examiner notes that Example II appears to be unexpectedly better than Comparative Example B given the bubble stability of 2.5 versus the lack of a bubble, respectively. This apparent unexpected showing is only valid for the specifically claimed species of each component and the specific amounts of each component utilized. Thus, these showing are insufficient to establish unexpected results of the claimed subject matter for various reasons as discussed below.

14. Firstly, the unexpected results are not commensurate in scope with the claimed invention, applicant's claims are generic to the claimed components, whereas the examples are drawn to species of the claimed components. For example, the claims are open to a polyolefin layer consisting essentially of polypropylene, whereas the examples do not even test polypropylene. Secondly, applicant has claimed open ranges for the ratio of the components present in the polyolefin layer, whereas the examples are drawn to specific amounts of each of the components (90 wt% LLDPE

and 10 wt% Yparex). Attention is directed to MPEP § 716.02(d)(I), which states that nonobviousness of a genus or claimed range may be supported by data showing unexpected results from testing a narrower range if one of ordinary skill in the art would be able to determine a trend in the exemplified data which would allow the artisan to reasonably extend the probative value thereof. However, applicants have failed to provide an adequate basis for reasonably concluding that the great number and variety of compositions included in the claims would behave in the same manner as the tested composition.

15. Furthermore, in regards to the comparison of comparison of Example II against Comparative Experiment B, as per MPEP § 716.01(d), in making a final determination of patentability, evidence supporting patentability must be weighed against evidence supporting *prima facie* case. The *prima facie* case of obviousness is based on the multi-layer of Bayer comprising a branched polyamide layer and a polyolefin layer, wherein it would have been obvious to have polypropylene or LLDPE as the polyolefin layer (as taught by Johnston). Applicants have not provided rebuttal evidence against the facts on which the conclusion of the *prima facie* case is established. Correspondingly, applicants have not compared the claimed subject matter with the closet prior art, as per MPEP § 716.02(e). Thus, the comparison of Example II against Comparative Experiment B is insufficient to overcome the prior art rejection.

16. Applicant has attempted provided rebuttal evidence against the facts on which the conclusion of the *prima facie* case is established by citing the comparison of Examples 1 and 2. Applicant has argued that the 0.4 difference in blow-up ratio of Example 1 and Example 2 is of technical significance and this difference is due to the presence or lack thereof of LDPE. The comparison of Example 1 and 2 is insufficient to overcome the prior art rejection for at least the lack of commensuration in scope with the claimed invention and open ranges, as discussed above.

Additionally, even though the 0.4 difference may be of technical significance, it does not indicate unexpected results. As per MPEP § 716.02, any differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected. *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant has failed to provide any evidence that such a difference is unexpected, modification of components comprising the film are expected to alter the blow-up ratio. The evidence fails to establish that the differences are in fact unexpected, unobvious, and of both statistical and practical significance. Even though the data maybe of statistical and practical significance, the test is four pronged and requires unexpected and unobvious differences to be present. Such unexpected and unobvious differences are absent in the comparison of Examples 1 and 2. Thus, the comparison of Example I against Example II is insufficient to overcome the prior art rejection.

17. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). It is noted that Bayer disclosed polyethylene as a suitable polyolefin (thus polyethylene usable in blow molding), thus there is a reasonable expectation LLDPE is suitable for use in blow molding (5:65-6:23). Furthermore, Johnston discloses that polypropylene can be blow molded, thus, there is a reasonable expectation that utilizing polypropylene in the combination taught by Bayer and Johnston would have been successful (1:42-45).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAIRA HAIDER whose telephone number is (571)272-3553. The examiner can normally be reached on Monday-Friday from 10am-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James J. Seidleck/
Supervisory Patent Examiner, Art Unit 1796

Saira Haider
Examiner
Art Unit 1796